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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,603	12/19/2001	Napoleone Ferrara	GENENT.1516CP1	4344

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,603	FERRARA ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80-85,94-100,104 and 106-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80-85,94-100,104 and 106-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 80-85, 94-100, 104 and 106-108 are pending.

2. The filing date of the instant claims 80-84, 94-99 and 104 is deemed to be the filing date of instant application if applicant desires priority prior to 9/7/2000 because none of the provisional applications have support for the limitation of "an antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells" as set forth in claim 80, "The antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells wherein the antibody is a monoclonal antibody" as set forth in claim 81, "The antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells wherein the antibody is a chimeric antibody" as set forth in claim 82, "The antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells wherein the antibody is a humanized antibody" as set forth in claim 83, "The antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells wherein the antibody fragment is a Fab, Fab', F(ab/)2 or Fv fragment" as set forth in claim 84, "A composition comprising the antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells in admixture with a carrier" as set forth in claim 94, "A composition comprising the antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells in admixture with a carrier wherein the carrier is a pharmaceutically acceptable carrier" as set forth in claim 95, "The composition comprising the antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells in admixture with a carrier wherein the antibody is a monoclonal antibody" as set forth in claim 96, "The composition comprising the antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells in admixture with a carrier wherein the antibody is a chimeric antibody" as set forth in claim 97, "The composition comprising the antibody or antibody fragment thereof that specifically binds residues *20-105* of

SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells in admixture with a carrier wherein the antibody is a humanized antibody" as set forth in claim 98, "The composition comprising the antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells in admixture with a carrier wherein the antibody fragment is a Fab, Fab', F(ab')2, or Fv fragment" as set forth in claim 99, "An article of manufacture comprising (a) a container, (b) a label on the container, and (c) the composition comprising the antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells and a pharmaceutically acceptable carrier" as set forth in claim 104, and "An antagonist of EG-VEGF wherein the antagonist comprises an antibody or antibody fragment that specifically binds a polypeptide comprising SQ ID NO: 2 and inhibits EG-VEGF induced enthothelial cell proliferation" as set forth in claim 108. Applicant is invited to point out and provide documentary support (i.e. page and line number) for the priority of the instant claims 80-84, 94-99 and 104 in 60/213,637, PCT/US/00219, 60/145,698, US99/12252, and 60/096,146.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 80-84, 94-99 and 104 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat No 6,485,938 B1 (filed November 16, 1999; PTO 892).

The '938 patent teaches various antibodies such as monoclonal (See col. 46, lines 52-62, in particular), humanized, chimeric antibody (See col. 48, lines 44-53, in particular) and binding fragment thereof such as F(ab')2, Fab', Fv, scFv (see col. 47, lines 22-66, in particular) that binds to the native full-length human Zven comprising SEQ ID NO: 5 that has amino acid sequence 100% identical to the claimed amino acid sequence of SEQ ID NO: 2 (See col. 54, line 67 bridging col. 55, SEQ ID NO: 5 of '938 patent, col. 51, line 13-14, in particular). Given the long stretch of identical amino acid residues 20-105, the reference antibody would also bind to the residues 20-105 of claimed SEQ ID NO: 2. Since the Patent Office does not have the facilities

for examining and comparing the antibodies of the instant invention to those of the prior art, the burden is on applicant to show that the prior art antibody is different from the claimed antibody. See In re Best, 562 F.2d 1252, 195 USPQ 430(CCPA 1977). The '938 patent further teaches a kit or article of manufacture comprising the reference antibody, a container and written instructions for using the reference antibody (See col. 54, lines 36-52, in particular). The '938 patent further teaches a compositon comprising the reference antagonist antibody such as anti-Zven2 antibody and injectable solution (See col. 57, lines 22-36, in particular). Thus, the reference teachings anticipate the claimed invention.

Applicants' arguments filed 9/5/05 have been fully considered but are not found persuasive.

Applicants' position is that the present application claims priority to a number of patent applications including provisional application 60/145,698 (July 26, 1999). The filing of the '298 application (July 26, 1999) predates the earliest priority date of the '938 patent. In the '698 application (EG-VEGF (SEQ ID NO: 2) is referred to as PRO1186 (SEQ ID NO: 165). The '698 application describes the amino acid and nucleotide sequence for EG-VEGF (see for example 278-279, and Figures 65 and 66), discloses that amino acids 1-19 of SEQ ID NO: 2 comprises a signal sequence (page 279, lines 4-5), demonstrates that EG-VEGF induces proliferation of ACE cells (see for example pages 18-19) and 208-215).

In response, it is noted that the claims are amended now recites "an antibody or antibody fragment thereof that specifically binds residues *20-105* of SEQ ID NO: 2 and inhibits EG-VEGF induced proliferation of endothelial cells" as set forth in claim 80, not the polypeptide as argued. Further, the specific residues such as "20 to 105" of SEQ ID NO: 2 to which the claimed antibody such as monoclonal, chimeric, humanized antibody and binding fragment thereof binds are not disclosed in the provisional application 60/145,698 (July 26, 1999).

5. Claims 80-85, 100 and 106-108 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-17 of copending Application No. 10/305,654. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species of antibodies to EG-VEGF such as monoclonal, humanized, chimeric and binding fragment thereof that binds specifically to EG-VEGF comprising SEQ ID NO: 2 or from residues 20-105 of SEQ ID NO: 2 anticipate the genus of antibody that specifically binds to SEQ ID NO: 172 of copending application 10/431,805. The

polypeptide of SEQ ID NO: 172 of copending application is 100% identical to instant polypeptide of SEQ ID NO: 2. The antibody made using either polypeptide would bind to each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants' arguments filed 2/17/06 have been fully considered but are not found persuasive.

Applicants' position is that the present application was filed December 19, 2001, while copending Application No. 10/205,654 was filed November 26, 2002. The present application is therefore the earlier filed of the two applications. The Examiner should withdraw the provisional ODP rejection and permit the earlier filed application to issue as a patent without a terminal disclaimer. MPEP § 804(I)(B)(1).

In response, if a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn, see MPEP § 804(I)(B)(1). However, the instant earlier-filed application is not in condition for allowance because Claims 80-84, 94-99 and 104 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat No 6,485,938 B1 (filed November 16, 1999; PTO 892).

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

8. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 28, 2006

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